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UNITED STATES PATENT APPLICATION

of

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for

STENT DELIVERY CATHETER WITH GROOVED BALLOON AND METHODS OF MAKING SAME

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FIELD OF THE INVENTION

[0001] The invention relates to intraluminal stenting, and in particular, to a catheter having a grooved stent delivery balloon.

BACKGROUND OF THE INVENTION

[0002] Intraluminal stenting is useful in treating tubular vessels in the body which are narrowed or blocked and it is an alternative to surgical procedures that intend to bypass such an occlusion. When used in endovascular applications, the procedure involves inserting a prosthesis into an artery and expanding it to prevent collapse of the vessel wall.

[0003] Percutaneous transluminal angioplasty (PTCA) is used to open coronary arteries which have been occluded by a build-up of cholesterol fats or atherosclerotic plaque. Typically, a guide catheter is inserted into a major artery in the groin and is passed to the heart, providing a conduit to the ostia of the coronary arteries from outside the body. A balloon catheter and guidewire are advanced through the guiding catheter and steered through the coronary vasculature to the site of therapy. The balloon at the distal end of the catheter is inflated, causing the site of the stenosis to widen. Dilation of the occlusion, however, can form flaps, fissures or dissections which may threaten re-closure of the dilated vessel. Implantation of a stent can provide support for such flaps and dissections and thereby prevent reclosure of the vessel. Reducing the possibility of restenosis after angioplasty reduces the likelihood that a secondary angioplasty procedure or a surgical bypass operation will be necessary.

[0004] A stent is typically a hollow, generally cylindrical device formed from wire(s) or a tube and the stent is commonly intended to act as a permanent prosthesis. A stent is deployed in a body lumen from a radially contracted configuration into a

radially expanded configuration which allows it to contact and support a body lumen. The stent can be made to be either radially self-expanding or expandable by the use of an expansion device. The self expanding stent is made from a resilient material while the device-expandable stent is made from a material which is plastically deformable. A plastically deformable stent can be implanted during an angioplasty procedure by using a balloon catheter bearing the compressed stent which has been loaded onto the balloon. The stent radially expands as the balloon is inflated, forcing the stent into contact with the body lumen, thereby forming a support for the vessel wall. Deployment is effected after the stent has been introduced percutaneously, transported transluminally and positioned at a desired location by means of the balloon catheter.

[0005] A balloon of appropriate size and pressure is first used to open the lesion. The process can be repeated with a stent loaded onto a balloon. Direct stenting involves simultaneously performing angioplasty and stent implantation using a stent mounted on a dilatation balloon. After the balloon is withdrawn, the stent remains as a scaffold for the injured vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the appended drawings in which:

FIG. 1 is a longitudinal view of a balloon in accordance with the invention;

FIGS. 2-5 are enlarged, longitudinal portions (FIGS. 2, 4 and 5 in section) of balloons in accordance with the invention, showing several alternative embodiments of circumferential grooves;

FIG. 6 is a longitudinal view of a balloon catheter in accordance with the invention, shown with the balloon deflated;

FIG. 7 is a longitudinal view of a stent delivery balloon catheter in accordance

with the invention, shown with a stent mounted thereon and the balloon deflated; and

FIG. 8 shows the embodiment of FIG. 7 wherein the balloon has been inflated to deliver the stent in a vessel of a patient.

DETAILED DESCRIPTION OF THE INVENTION

[0007] Applicant's invention is useful with any expandable stent, such as those stents designed for delivery by a balloon. The stent may be generally cylindrical, and it may be mounted on a tubular balloon. FIG. 1 shows balloon 10, which can retain a stent thereon during delivery. Proximal and distal circumferential grooves 15, 20, respectively, surround balloon 10 adjacent the transitions between intermediate body 12 and proximal and distal cones 25, 30, respectively. Intermediate body 12 may be generally cylindrical in shape, and it may be centrally located between proximal and distal cones 25, 30. Proximal and distal cones 25, 30 terminate in proximal and distal ends 35, 40, respectively, which are adapted to be mounted on catheter shaft 50, as shown in FIG. 6.

[0008] In FIG. 1, proximal circumferential groove 15 is substantially U-shaped when viewed in longitudinal section, and the diameters of balloon 10 measured distal and proximal to groove 15 are substantially equal. Distal circumferential groove 20 is an alternative embodiment to groove 15 and is flat-bottomed, or rectangular in longitudinal section. FIGS. 2-5 show several other alternative embodiments of circumferential grooves in balloon 10. As shown in FIG. 2, circumferential groove 115 is substantially C-shaped in longitudinal section. Groove 115 may also be described as being generally circular in longitudinal section, with an open arc portion. Groove 115 is also shown as being optionally filled with flexible material 45. Any of the circumferential grooves in the invention may be partially or fully filled with flexible material 45, as will be described further below.

[0009] As shown in FIG. 3, circumferential groove 215 is substantially U-

shaped in longitudinal section. However, groove 215 is located toward the cone side of the transition between cylindrical intermediate body 12 and cone 225, such that the diameters of balloon 10 measured distal and proximal to groove 215 are substantially unequal.

[0010] As shown in FIG. 4, circumferential groove 315 is substantially W-shaped in longitudinal section. Groove 315 may also be considered as two U-shaped circumferential grooves formed adjacent each other. As shown in FIG. 5, circumferential groove 415 is, in longitudinal section, a polygon with an open side.

[0011] Balloon 10 can be made according to stretch blow molding processes that are well known to those skilled in the arts of dilatation and stent delivery balloons. Molds used in balloon forming typically have hollow intermediate sections with removable end inserts for forming cones, and are made of metal such as brass. In known alternatives, balloon molds may be unitary tubular chambers that have been thermo-formed of a high temperature material such as glass. Circumferential grooves 15, 20, and their alternatives shown herein can be formed during conventional stretch blow molding, thus providing a generally uniform wall thickness throughout the balloon regions that include grooves 15, 20.

[0012] A balloon mold can be adapted in a variety of ways to form balloon 10 with circumferential grooves 15, 20. In a first example, ring members may be inserted inside a balloon mold such that balloon 10 forms around the ring members to create circumferential grooves 15, 20. The ring members can be cast, molded or machined of any material that will retain its shape during balloon forming, such as a metal, a ceramic, a thermoset polymer or a thermoplastic having a sufficiently high melting temperature. A conventional multi-part mold may have one or more internal grooves adapted to retain the ring members in the desired position within the mold. For instance, ring retaining grooves may be machined adjacent the interface between a mold center section and the mating removable inserts. In a second example, a unitary glass balloon mold (see U.S. Patent No. 5,163,989) can be formed to capture

the ring members within the inner chamber. Balloon 10 can be made from single or multiple layers of thermoplastics such as polyolefins, polyurethanes, polyamides, blends or block copolymers that include these materials, or other polymers known to be suitable for dilatation and stent delivery balloons.

[0013] Circumferential grooves 15, 20 create a partial mechanical disengagement between balloon intermediate body 12 and cones 25, 30. The partial disengagement permits adjacent body 12 and cones 25, 30 to move differently in the radial direction, comparable to the way a rolling diaphragm works in the axial direction. For example, if intermediate body 12 is radially restrained during inflation of balloon 10, then circumferential grooves 15, 20 will allow a limited radial expansion of cones 25, 30, thus creating radial steps at both ends of intermediate body 12. These radial steps can be heat set into balloon 10, and can act as dams to prevent stent 60 from sliding off of balloon 10.

[0014] Any of the circumferential grooves disclosed herein can be partially or completely filled with flexible material 45, as mentioned above. The addition of such a material to a circumferential groove can reinforce or enhance the dam effect created by the radial steps at the ends of intermediate body 12. Substances selected for flexible material 45 may be elastic or inelastic, thermoplastic or thermoset polymers, and may be foamed to enhance flexibility. Flexible material 45 may also comprise a formulation typically used for coating medical devices, including balloons, to either reduce or enhance friction properties. Elastic or elastomeric materials may provide a high coefficient of friction relative to the material of balloon 10, thus enhancing stent retention thereon. To avoid separation between flexible material 45 and balloon 10, material 45 should be adhered to balloon 10, either by inherent adhesive properties of the material, or by a separate bonding component.

[0015] FIG. 7 shows a stent delivery balloon catheter in accordance with the invention, and which has been made as follows. Balloon 10 is mounted on catheter shaft 50. Balloon 10 is deflated about shaft 50, and stent 60 is crimped or compressed

about intermediate body 12. With stent 60 held in the radially compressed configuration, inflation pressure is applied to balloon 10. In response to this internal pressure, circumferential grooves 15, 20 allow limited expansion of cones 25, 30 to form proximal and distal steps 65, 70, respectively. Heat setting of balloon 10 imparts thereto a memory of the shapes of steps 65, 70. Heat setting can be performed with or without internal pressure in balloon 10.

[0016] Alternatively, steps 65, 70 may be formed after deflation of balloon 10 by wrapping balloon 10 around shaft 50 and crimping stent 60 around intermediate body 12. During stent crimping, circumferential grooves 15, 20 allow cones 25, 30 to retain a larger deflated profile than that of intermediate body 12. In this way, steps 65, 70 can be formed without pressurizing balloon 10.

[0017] The invention may be practiced with one or more circumferential grooves adjacent the ends of intermediate body 12 of balloon 10. For example, a single groove 20 may be formed in balloon 10 adjacent the transition between intermediate body 12 and distal cone 30. Alternatively, a single groove 15, may be formed in balloon 10 adjacent the transition between intermediate body 12 and proximal cone 25. As shown in FIG. 4, two or more grooves may be formed next to each other adjacent a transition between intermediate body 12 and a cone. Any combinations of alternative embodiments of circumferential grooves are also possible, with or without flexible filler materials.